

## **REMARKS**

The Office Action of May 19, 2004, has been considered by the Applicants. Claims 1, 4, 7, 8, 10, 12, 29, and 31-33 have been amended. Claims 3 and 9 have been cancelled. Claims 1-2, 4-8, and 10-33 remain pending in the Application. Reconsideration of the Application is requested.

### **1. The Office Action**

The Examiner has rejected claims 1-3, 12, 15, 16, 19-22, 24, and 26-28 as being anticipated over Ebert et al. (U.S. Patent No. 4,532,126); claims 4-6 and 25 as being obvious over Ebert et al.; claims 7-12, 14, 17-18, and 29-31 as being obvious over Ebert et al. in view of Romanczyk Jr. (U.S. Patent No. 6,297,273); claim 32 as being obvious over Ebert et al. in view of Perry et al. (EP 0 904 064 B1); claim 33 as being obvious over Ebert et al. in view of Wada et al. (JP 7-242536); and, claims 13 and 23 as being obvious over Ebert in view of Pasquale (U.S. Patent No. 4,921,843).

### **2. Features of The Claimed Invention**

The claimed invention relates to a chewable soft capsule with improved ingestion properties. This is achieved by the use of a soft capsule and a fill material, comprising a low melting point additive, which is solid or semi-solid at room temperature. The low melting point additive comprises chocolate base, or chocolate base in combination with lard, coconut oil or macrogol (polyethylene glycol). The chocolate base may be cocoa powder, bitter chocolate, cocoa butter or a combination thereof.

### **3. Analysis of The Cited References**

Ebert et al. discloses a soft elastic gelatin capsule containing, preferably, a liquid fill material (col. 2, line 42, and col. 4, line 5). Ebert et al. fails to teach or suggest a solid or semi-solid fill material at room temperature, or a low melting point fill material comprising chocolate base.

Romanczyk Jr. merely discloses the advantageous properties of many cocoa extracts. In col. 75, lines 5-8, the composition of capsules containing the desired cocoa

extracts are described. The extract is suspended in a “suitable liquid” to form a fill material for the capsule. Romanczyk Jr. fails to teach or suggest a solid or semi-solid fill material.

Perry et al. discloses soft or hard capsules containing a drug in a “liquid formulation” (page 0013). The cited reference further describes that a “liquid formulation” is preferred, as the drug is presented to the body in the most available form, and it avoids problems of slow disintegration and dissolution associated with solid oral dosage formulations” (page 0013). Perry et al. fails to teach or suggest a solid or semi-solid fill material or a low melting point fill material comprising chocolate base.

Wada et al. discloses gelatin capsules containing a drug component which is “preferably supported in an aqueous liquid carrier”. Wada et al. fails to teach or suggest a solid or semi-solid fill material or a low melting point fill material comprising chocolate base.

Pasquale merely describes a contraception system, wherein the hormones can be administered to the patient in the form of a tablet, capsule or pill. While Pasquale describes the addition of a sweetener such as aspartame, the cited reference is silent as to the state of the sweetener (i.e., solid, semi-solid, or liquid) or its location within the capsule (i.e., the shell or the fill).

#### 4. Rebuttal Position

Claims 1-3, 12, 15, 16, 19-22, 24, and 26-28 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,532,126 to Ebert. Applicants traverse the rejection.

To anticipate, a reference must teach every element of the claim. MPEP § 2131. Claim 1 teaches a fill material in a solid or semi-solid form at room temperature. Ebert does not teach such a fill material. Instead, Ebert states that his invention is directed to a SEG capsule containing a liquid fill. Because he teaches a liquid fill rather than a solid or semi-solid fill material, Ebert does not anticipate claim 1 as amended.

Further, Ebert et al. fails to teach or suggest a low melting point fill material comprising chocolate base, as is recited in amended claim 1.

Because the remaining claims are ultimately dependent on claim 1 and claim 1 is not anticipated, they are also not anticipated. Applicants request withdrawal of the rejections.

Claims 4-6 and 25 were rejected under 35 U.S.C. 103(a) as obvious over Ebert. According to the Examiner, Ebert teaches overlapping ranges. Applicants traverse the rejections.

Claims 4-6 and 25 ultimately depend on claim 1, which was not rejected by the Examiner as being obvious. Because claim 1 is not obvious, any dependent claims are not obvious. MPEP § 2143.03. Applicants request withdrawal of the rejections.

Claims 7-12, 14, 17, 18, and 29-31 were rejected under 35 U.S.C. 103(a) as obvious over Ebert in combination with U.S. Patent No. 6,297,273 to Romanczyk, Jr. According to the Examiner, Romanczyk teaches the use of cocoa solids or fat in soft capsule formulations with sweeteners. Applicants traverse the rejections.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, all claim limitations must be taught or suggested. MPEP § 2143.03. Applicants submit that at least the first and third criteria have not been met.

There is no suggestion or motivation to combine Ebert and Romanczyk. Applicants note that Romanczyk is directed to the use of cocoa solids as anti-cancer agents, not as a candy or confectionary. In addition, Romanczyk does not teach that his cocoa solids are sweet or suitable for use as a candy. In Examples 38-40, where Romanczyk discusses tablet, capsule, and chocolate formulations, no mention is made of sweetness. Therefore, one would not read Ebert and look to use Romanczyk's anti-cancer agent as a candy or confectionary in Ebert's fill material. Similarly, one would not read Romanczyk and look to Ebert for a capsule formulation because Romanczyk already teaches a capsule formulation in Example 39.

Additionally, Romanczyk also teaches the use of a liquid fill material, not a solid or semi-solid material; see col. 75, lines 5-8. For these reasons, there is no motivation to combine Ebert and Romanczyk. Neither Ebert et al. nor Romanczyk Jr. teach or suggest a solid or semi-solid fill material. As described above, both cited references teach liquid fill materials. As such, the combination of Ebert et al. and Romanczyk Jr.

fails to teach the claim limitations of amended claim 1 and the claims which depend therefrom.

Claim 32 was rejected under 35 U.S.C. 103(a) as unpatentable over Ebert in combination with EP 0 904 064 to Perry. Perry allegedly teaches the use of coconut oil as a fill material.

Additionally, claim 33 was rejected under 35 U.S.C. 103(a) as unpatentable over Ebert in combination with JP 7-242536 to Wada. Wada reportedly teaches the use of macrogol as a fill material.

Claims 13 and 23 were rejected under 35 U.S.C. 103(a) as unpatentable over Ebert in combination with US 4,921,843 to Pasquale. Pasquale allegedly teaches the use of sodium saccharin and aspartame as a sweetener. Applicants traverse the rejections.

Claims 13 and 23 ultimately depend on claim 1. Because amended claim 1 is not obvious, neither are its dependent claims. MPEP § 2143.03.

Furthermore, the combination of Ebert et al. with either Perry et al., Wada et al., or Pasquale, fails to disclose the claimed inventions. In addition, Perry et al. and Wada et al. fail to teach or suggest a low melting point fill material comprising chocolate base.

Moreover, Perry et al. clearly teaches away from the claimed invention. As outlined above, the cited reference teaches the advantages of not using a solid fill material. As such, one skilled in the art would not be motivated to produce the claimed invention in light of the disclosure of Perry et al.

In addition, Pasquale merely describes a contraception system, and fails to describe the state (i.e., solid, semi-solid or liquid) of the sweetener or its location within the capsule (i.e., the shell or fill).

With specific regard to aspartame, the specification teaches an aspartame stabilizing effect when combined with cacao butter. This effect is not obvious and is not taught by Pasquale. Applicants request withdrawal of the rejections.

Finally, there are significant features of the claimed invention which are neither taught nor suggested by the cited references. For example, the superior ingestion properties of the claimed invention, as set forth in Examples 1-3, where the claimed capsules having solid or semi-solid fill material are compared with capsules having liquid fill material.

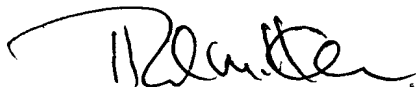
**CONCLUSION**

For the reasons detailed above, it is respectfully submitted all claims remaining in the application are now in condition for allowance. It is believed that no reexamination or new search is required. Withdrawal of the rejections and issuance of a Notice of Allowance is requested.

In the event the Examiner considers personal contact advantageous to the disposition of this case, he is hereby authorized to call Richard M. Klein, at telephone number 216-861-5582, Cleveland, OH.

Respectfully submitted,

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October 19, 2004  
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| Lynda S. Kalemba   |